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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,075	02/19/2004	Sean D. Monahan	Mirus.030.16.6	4417
25032	7590	07/11/2007		
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 07/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/782,075

Applicant(s)

MONAHAN ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 04/23/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 11/03/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 04/23/2007, claims 1 and 4-10 and 13-14 are pending in the application. Applicant has canceled claims 2-3 and 11-12.

### ***Response to Claim Rejections***

#### ***Re: Claim Rejections - 35 USC § 112***

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is obviated as the claim has been canceled.

#### ***Re: Claim Rejections - 35 USC § 102***

The rejection of claims 1, 4-6 and 13-14 under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (U.S. Patent No. 6,008,344) is maintained for the reasons of record in the action mailed 11/03/2006.

Applicant's arguments in the remarks filed 04/23/2007 are acknowledged but are not found persuasive. Applicant argues that while Bennett et al. does teach a list of chemical groups that may be added to an antisense RNA oligonucleotide, Bennett et al. do not teach that such groups may be used to enhance interaction of antisense RNA with a transfection agent. Applicants further argue that while Bennett et al. teach that a cholesterol moiety may enhance the activity of an oligonucleotide, Bennett et al. do not teach that cholesterol or any other modification may increase the interaction of the oligonucleotide with a transfection agent.

As discussed in the action mailed 11/03/2007 and reiterated here, the specification, at page 3 line 25, discloses a method of altering the interaction of an oligonucleotide with a cell or transfection agents comprises reacting the oligonucleotide with a modifying agent wherein the modifying agent contains a hydrophobic group. Therefore, based on the definition of altering the interaction of an oligonucleotide with a transfection agent disclosed in the instant specification, Bennett et al. anticipates the instantly claimed invention because Bennett et al. teach chemically linking a lipid moiety such as a cholesterol moiety to the antisense RNA and because cholesterol moieties are lipid molecules that are hydrophobic, this would meet the limitation of altering the interaction of the RNA with the transfection reagent.

Applicants' further argue that Bennett et al. do not teach or suggest the labile modification of an antisense RNA and therefore Bennett et al. cannot anticipate the instant claims. A labile bond is disclosed as a bond as being a bond that is a cleavable bond that is capable of being broke under certain conditions, as specifically defined on

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page 13, line 6. Because the specification does not specifically define what selective conditions would break the labile bond, a labile bond is being interpreted to mean any bond that is capable of being broken. Bennett et al. teach post-synthetically modifying a RNA by attaching via a bond at the 2'-hydroxyl position with one or more functional groups, and because this bond would be capable of being broken under certain conditions, the bond taught by Bennett et al. would be a labile bond and anticipate the instant claims.

***Re: New Claim Rejections - 35 USC § 103***

The rejection of claims 1, 4-10 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (U.S. Patent No. 6,008,344), Tuschl et al. (cited on PTO form 892 filed 11/29/2005), Hammond et al. (Nature, 2001, Vol. 2, 110-119) and Goldsborough (cited on PTO form 892 filed 11/29/2005) and as evidenced by Letsinger et al (PNAS 1989) is maintained for the reasons of record in the action mailed 11/03/2006.

Applicant relies on the arguments above against Bennett et al. and as discussed above, they arguments are not found persuasive.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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